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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,120	06/27/2003	Wing Ming Keung	11187-00016	6701
27716	7590	11/22/2005	EXAMINER	
CV THERAPEUTICS, INC. 3172 PORTER DRIVE PALO ALTO, CA 94304			OWENS, AMELIA A	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,120

Applicant(s)

KEUNG ET AL.

Examiner

Amelia A. Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-1-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-32 are pending.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1-32 under 35 USC 102(b) over Vallee et al is dropped. The Vallee compounds are not encompassed by the present claims.
3. The rejection of claims 1-3,6-13,16-23,26-28,31,32 under 35 USC 102(b) over Zheng et al is dropped. The Zheng et al compounds are not encompassed by the present claims.
4. The rejection of claims 1-3,6-13,16-23,26-28,31,32 under 35 USC 102(b) over Pei et al is dropped. The Pei et al compounds are not encompassed by the present claims.
5. The rejection of claims 26-28,31,32 under 35 USC 102(b) over Ito et al is dropped. The Ito et al compounds are not encompassed by the present claims.
6. The rejection of claims 26-28,31,32 under 35 USC 102(b) over Blaise et al - (FR 21904211) is dropped. The Blaise et al compounds are not encompassed by the present claims.
7. The rejection of claims 26,27,29,31,32 under 35 USC 102(b) over Jagdish et al is dropped. The Jagdish et al compounds are not encompassed by the present claims.

Claim Rejections - 35 USC § 112

8. The rejection of claims 1,7,17,26 under 35 USC 12, 1st paragraph, as failing to comply with the written description requirement *as the claims contain new matter* is dropped. The proviso language covers daidzein, compound 40 @ page 17 of the specification. Since the compound was specifically named in the specification, it may be specifically excluded.
9. Claims 1-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' remarks have been fully considered but are not found persuasive. The rejection includes all of the claims. Claims 2,4,5,18 were erroneously omitted. The enzyme patents are noted. However, patents USP 5885028, 5783189 in the ALDH art are directed to

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treating alcohol abuse; reducing alcohol consumption; treating alcohol dependence. The thrust of applicants invention is the same according to the specification @ page 2, summary of the invention.

Further, patent application 09/616718 seeks to reduce alcohol consumption by increasing the concentration of 5-hydroxyindole-3-acetaldehyde or 3,4-dihydroxyphenyl-acetaldehyde formed during cabolism of the *neurotransmitters* serotonin or dopamine.

The claims contain the terms 'inhibiting', 'modulation', 'modulates', 'identifying' that per se are not a utility. What effect are applicants trying to achieve? What is the desired end result?

The language -- 'inhibiting ALDH-2 comprising contacting ALDH2'; 'modulating ALDH-2 comprising contacting ALDH-2'; 'inhibiting ALDH-2'; 'identifying a compound that modulates ALDH-2' -- encompasses as yet unidentified diseases/conditions caused by or related to ALDH-2 'inhibition, modulation, identifying', a description of which is not found in the specification.

In addition, claims 7-18 encompass as yet unidentified neurotransmitters, a description of which is not found in the specification. It is suggested that dopamine and serotonin replace the term.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

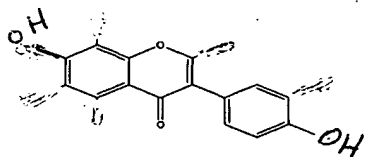
10. Claims 7-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims use the term 'modulating' or 'modulates' which is ambiguous. 'Modulating' and 'modulates' encompasses enhancement and inhibition. No single compound can perform both functions simultaneously. It is noted that the specification is directed to 'reducing' alcohol intake.

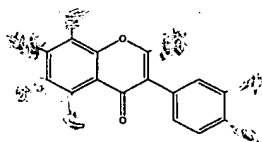
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Certain Observations

11. Daidzin is known to suppress alcohol intake and has the following structure.



Thus compounds having the core structure would be expected to suppress alcohol intake as compounds similar in structure depicted below would be expected to have similar properties. It is noted that other daidzin derivatives also suppress alcohol intake which further provides expectation that the claimed daidzin compounds would suppress alcohol intake.



The prior art neither teaches nor suggests the claimed compounds. Motivation is lacking to modify the prior art thereby arriving at the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amelia A. Owens
Primary Examiner
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